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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXPEDITE

APR 26 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3476/FAP#7H5524. Myclobutanil in or on Apples, Grapes, Their By-Products, Meat, Milk, and Eggs.

Follow-up to the RCB New Chemical Residue Chemistry Review of Myclobutanil (RH-3866) dated 2/8/88.

RCB Nos.: 3431-3435; 3560-3573.

MRID Nos.: 404975-00, -01; 405481-00, -01.

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This review is being expedited at the request of the Registration Division (memo of E. Tinsworth, 3/28/88). The due date for its completion is 5/9/88.

This review is of myclobutanil residue chemistry data received by RCB between February 6, 1988 (February 5, 1988 was the cut-off date imposed by the previous RCB residue chemistry review, issued February 8, 1988) and April 25, 1988.

Myclobutanil is a new chemical, and this petition proposes the first food-use permanent tolerances.

RCB's previous review of myclobutanil residue chemistry data (2/8/88) was formatted to serve as a Registration Standard for Myclobutanil. This current review is in RCB standard petition amendment format.

Once the remaining deficiencies raised by RCB have been adequately addressed by the petitioner, a revised version of the "RCB New Chemical Residue Chemistry Review of Myclobutanil", will be issued in the Registration Standard Format.

That revision will be accompanied by Table A - Generic Data Requirements (40 CFR 158.125 - Residue Chemistry) for Myclobutanil.

This present review has no Attachments to it, and contains no confidential business information.

A Revised Version #1 (dated 4/11/88) of the 2/8/88 RCB New Chemical Product Chemistry Review of RH-3866 Technical (myclobutanil) was issued 4/13/88 (with 6 Confidential Appendixes).

That review was in Registration Standard format, and included a Table A of Product Chemistry Generic Data Requirements (40 CFR 158.120) for RH-3866 Technical.

EXECUTIVE SUMMARY OF REMAINING RESIDUE CHEMISTRY DEFICIENCIES TO BE RESOLVED FOR RCB

[NOTE: These deficiencies are discussed in full in the DETAILED CONSIDERATIONS section of this review; RCB's requirements to resolve these deficiencies are explained in detail in the CONCLUSIONS section (which follows this Executive Summary).]

Proposed Tolerances (See Conclusion #1, below)

- A revised Section F is needed.

Residue Analytical Methods (See Conclusion #3, below)

- A final judgment re the adequacy of proposed enforcement methods cannot be made until PMVs are completed, revised methods submitted, and evaluated.

- An enforcement method is needed for RH-9090 (bound) in milk.

Magnitude of the Residue - Apples (See Conclusion #5, below)

- A final judgment re the adequacy of submitted apple field trial and processing study data, and proposed tolerance levels, cannot be made until PMVs are completed, revised methods submitted, and evaluated.

- The raw data from apple trial 84-0238 should be submitted, if available.

Magnitude of the Residue - Grapes (See Conclusion #6, below)

- A final judgment re the adequacy of submitted grape field trial and processing study data, and proposed tolerance levels, cannot be made until PMVs are completed, revised methods submitted, and evaluated.

Magnitude of the Residue - Cattle (See Conclusion #7, below)

- A final judgment re the appropriate levels of tolerance cannot be made until PMV of proposed enforcement methodology for the regulable residue in animal commodities verifies an adequate level of recovery and sensitivity at (or below) the suggested tolerance levels (listed in Conclusion #1).

Magnitude of the Residue - Poultry (See Conclusion #8, below)

- A final judgment re the appropriate levels of tolerance cannot be made until PMV of proposed enforcement methodology for the regulable residue in animal commodities verifies an adequate level of recovery and sensitivity at (or below) the suggested tolerance levels (listed in Conclusion #1).

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CONCLUSIONS

1. A revised Section F is needed. While a final judgment re appropriate tolerance levels must await the completion of PMVs, any needed revisions to the methods, and their re-evaluation by RCB (and, if warranted, COB), tentatively, we can conclude the revised Section F should propose:

For 40 CFR 180.XXX:

a. Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in or on:

Apples.....0.5 ppm
Grapes.....1.0 ppm

b. Tolerances for combined residues of RH-3866 and its RH-9090 (free and bound) and diol metabolites in:

Milk.....0.05 ppm

c. Tolerances for combined residues of RH-3866 and its RH-9090 (free) metabolite in:

Meat, fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep).....0.05 ppm

Liver of cattle, goats, hogs, horses, and sheep.....0.3 ppm

Meat, fat, and meat byproducts of poultry.....0.02 ppm*

Eggs.....0.02 ppm*

[*NOTE: If the petitioner would prefer to propose a method sensitivity level tolerance of 0.01 ppm for poultry tissues and eggs, RCB would not object.]

For 21 CFR 193.XXX:

Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in:

Raisins.....10.0 ppm

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For 21 CFR 561.XXX:

Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in:

Apple pomace	5.0 ppm
Grape pomace	10.0 ppm
Raisin waste	25.0 ppm

2. Revised proposed labeling has been submitted for the formulated products:

707-ERE	RALLY™ 40W Fungicide
707-ERL	RALLY™ 40W Fungicide in 4 oz. Water-Soluble Pouches
707-ERR	RALLY™ 60DF Fungicide
707-EER	NOVA® 40W Fungicide in 5 oz. Water-Soluble Pouches

The appropriate revisions have been made. This deficiency is now resolved.

3. We continue to withhold judgment on the adequacy of the submitted analytical methods for residue data gathering and/or enforcement purposes pending completion of petition method validation (PMV) trials by COB/BUD chemists, review by RCB of COB's reports on such trials, corrective action (where needed) on the petitioner's part, and reevaluation by RCB (and, if warranted, COB).

A residue analytical method continues to be needed for the determination of RH-9090 (bound) in milk.

Based on the RCB and TOX decisions on the regulable residue (see TOX review of 4/5/88 and RCB review of 4/14/88), residue analytical methods are no longer being requested in re this petition for the hydroxylactone and diol (RH-0294) metabolites, or for RH-9090 (bound) in animal tissues other than milk.

4. The petitioner has set forth a convincing argument, supported by reanalyses of stored samples of apples and grapes, as to why the additional storage stability data requested are not needed.

RCB considers this additional information adequate to resolve this deficiency for purposes of this petition.

5. Only tentative conclusions can be reached at this time re the adequacy of submitted apple field trial and processing study data and proposed tolerance levels, pending PMV results and evaluation. Tentatively, it appears appropriate tolerance levels will be 0.5 ppm for apples and 5.0 ppm for apple pomace.

   Additionally, the petitioner should submit the raw data requested (apple trial 84-0238), if available, and verify the processing dates and storage intervals reported in TR 34S-88-11 for both apple trials (85-0542 and 84-0238).

6. Only tentative conclusions can be reached at this time re the adequacy of submitted grape field trial and processing study data and proposed tolerance levels, pending PMV results and evaluation. Tentatively, it appears appropriate tolerance levels will be 1.0 ppm for grapes, 10.0 ppm for grape pomace and raisins, and 25 ppm for raisin waste.

7. At the dietary burden (4.5-5.5 ppm/day to cattle) associated with the proposed use on apples and grapes, appropriate tolerances will be 0.05 ppm for milk and the meat, fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep; and, 0.3 ppm for liver of cattle, goats, hogs, horses, and sheep.

   This conclusion is contingent upon successful PMVs for the components of the regulable residue being conducted by COB/BUD, and demonstrating an adequate level of recovery and sensitivity at (or below) these suggested tolerance levels.

   A revised Section F proposing appropriate tolerances for the regulable residue will need to be submitted (see Conclusion #1).

8. At the dietary burden (0.75 ppm/day to poultry) associated with the proposed use on apples and grapes, appropriate tolerances will be 0.02 ppm [or 0.01 ppm, if the petitioner prefers to propose the level of method sensitivity] for eggs and the meat, fat, and meat by-products of poultry.

   This conclusion is contingent upon successful PMVs for the components of the regulable residue being conducted by COB/BUD, and demonstrating an adequate level of recovery and sensitivity at (or below) these suggested tolerance levels.

A revised Section F proposing appropriate tolerances for the regulable residue will need to be submitted (see Conclusion #1).

9. Revised Confidential Statements of Formula (3/11/88) have been submitted for RH-3866 Technical and the four formulated products (listed in Conclusion #2).

10. Dietary exposure estimates were considered; the need to regulate RH-9090 (bound) in milk was reaffirmed by TOX.

RECOMMENDATIONS

Since there are still outstanding deficiencies raised by RCB to be resolved in re this petition, RCB continues to recommend against the establishment of permanent tolerances for residues of myclobutanil and certain of its metabolites in or on apples, grapes, their byproducts, meat, milk, and eggs, at this time.

For further consideration of these tolerance requests, the petitioner should be advised by the PM of the need to respond to the unresolved deficiencies raised by RCB.

These deficiencies are listed in Conclusions 1, 3, 5, 6, 7, and 8 of this review.

An Executive Summary, briefly outlining the deficiencies, is also included in this review. (See "EXECUTIVE SUMMARY OF REMAINING RESIDUE CHEMISTRY DEFICIENCIES TO BE RESOLVED FOR RCB", beginning on page 2 of this review.)

[NOTE: Myclobutanil is a new chemical, and this petition represents the first food-use permanent tolerance requests.

Once all deficiencies are resolved, the Residue Chemistry review in Registration Standard format will be appropriately revised and reissued. A Table A will also be provided at that time.]

DETAILED CONSIDERATIONS

The deficiencies raised in the RCB New Chemical Residue Chemistry Review of Myclobutanil (RH-3866), 2/8/88, are listed in sequence below, followed by the petitioner's response, and RCB's comments/ conclusions to that response.

DEFICIENCY: Proposed Tolerances

A revised Section F is needed. Provided the storage stability issue is satisfactorily resolved and petition method validations (PMVs) are successful, it should propose:

For 40 CFR 180.XXX:

a. Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in or on:

Apples	0.5 ppm
Grapes	1.0 ppm

b. Tolerances for combined residues of RH-3866 and its RH-9090 (free and bound) and diol metabolites in:

Milk	0.05 ppm

c. Tolerances for combined residues of RH-3866 and its RH-9090 (free and bound), diol, and hydroxy-lactone metabolites in:

Meat, fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep)	0.05 ppm
Liver of cattle, goats, hogs, horses, and sheep	0.3 ppm
Meat, fat, and meat byproducts of poultry	0.02 ppm
Eggs	0.02 ppm

For 21 CFR 193.XXX:

Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in:

Raisins.....10.0 ppm

For 21 CFR 561.XXX:

Tolerances for combined residues of RH-3866 and its metabolite RH-9090 (free and bound) in:

Apple pomace.....5.0 ppm
Grape pomace.....10.0 ppm
Raisin waste.....25.0 ppm

PETITIONER'S RESPONSE: Proposed Tolerances [MAM 88-19]

The petitioner requested RCB reconsider its position re what the regulable residue should be comprised of in animal commodities.

The petitioner also requested RCB reconsider the need to set tolerances in poultry tissues and eggs.

The petitioner indicated a revised Section F would be submitted following this reappraisal by RCB.

RCB'S COMMENTS/CONCLUSIONS: Proposed Tolerances

RCB has reexamined the need to establish tolerances for poultry tissues and eggs. We categorize the poultry metabolism/feeding study data in 40 CFR 180.6(a)(2). Thus, at a minimum, method sensitivity level tolerances do need to be set. RCB would find a proposed tolerance level of either 0.02 (2X method sensitivity) or 0.01 (method sensitivity) ppm to be acceptable for poultry tissues and eggs, whichever level the petitioner prefers.

RCB has also reconsidered the issue of the regulable residue in animal commodities, as the petitioner requested. After further discussions with TOX, it has been jointly decided (TOX/RCB) the following residues warrant regulation (see TOX review, 4/5/88, and RCB review, 4/14/88) in animal commodities:

Meat, Fat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, Poultry, and Sheep; Eggs.	RH-3866 RH-9090 (free)

Milk	RH-3866 RH-9090 (free) RH-9090 (bound) RH-0294 (diol)

And, to recap, the following residues warrant regulation in the crop commodities of this petition:

Apples, Apple Pomace; Grapes, Grape Pomace; Raisins, Raisin Waste.	RH-3866 RH-9090 (free) RH-9090 (bound)

CONCLUSION: This deficiency has not yet been resolved. An appropriately revised Section F needs to be submitted.

DEFICIENCY: Directions for Use

The proposed Directions for Use on apples of Rally™ 40W (EPA Reg. No. 707-ERE), Rally™ 60DF (EPA Reg. No. 707-ERR), and Nova™ 40W in Water-Soluble Pouches (EPA Reg. No. 707-EER) need to be revised to:

1. Add information on the use rates in terms of ozs or lbs ai/A.

2. Delete reference to use of a concentrate spray, unless the petitioner can supply data from apple field trials reflecting use of concentrate sprays of these formulations.

3. Express spray volumes in terms of tree row volume rather than tree height. The petitioner is advised to consult the Attachment to this review entitled, "Guidance for Orchard Spray Application", for advice in preparation of revised labels using this procedure.

4. Specify on the labeling that all tank mates must be cleared (i.e., have established tolerances) by EPA for use on apples.

Additionally, the proposed Directions for Use on apples of Nova™ 40W in Water-Soluble Pouches also needs to be revised to limit use to application by ground equipment only.

A revised Section B for this petition incorporating these requested label changes needs to be submitted.

The proposed Directions for Use on grapes of Rally™ 40W (EPA Reg. No. 707-ERE), Rally™ 40W in Water-Soluble Pouches (EPA Reg. No. 707-ERL), and Rally™ 60DF (EPA Reg. No. 707-ERR) need to be revised to:

1. Add information on the use rates in terms of ozs or lbs ai/A.

2. Specify on the labeling that all tank mates must be cleared (i.e., have established tolerances) by EPA for use on grapes.

A revised Section B for this petition incorporating these label changes for each of these formulations needs to be submitted.

PETITIONER'S RESPONSE: Directions for Use [MRID # 405481-00]

The petitioner has submitted revised proposed labeling for each of the aforecited products.

RCB'S COMMENTS/CONCLUSIONS: Directions for Use

The petitioner's revised labeling incorporates all the changes RCB requested. The proposed use pattern (rates, timing, etc.) remains unchanged.

CONCLUSION: This deficiency is now resolved.

DEFICIENCY: Residue Analytical Methods

Residue analytical methods have been submitted for the determination of RH-3866, RH-9089, and RH-9090 (free and conjugated) in apples and grapes (TR 310-84-27, with Addendums TR 31H-86-15 and TR 31S-87-46); RH-9090 (free only) in crops and RH-3866 in crops, meat, milk, and eggs (TR 310-84-13, with Addendum TR 310-86-09); RH-9090 (free only) in meat, milk, and eggs (TR 31S-87-09); and, RH-0294 (diol) in milk (TR 31S-87-02).

We withhold judgment on the adequacy of these analytical methods for residue data gathering and/or enforcement purposes pending completion of method validations by COB/BUD chemists, and receipt/review by RCB of the report(s) from COB on the results of these validations.

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Residue analytical methods are also needed for the determination of RH-9090 (conjugated) in milk, and RH-9090 (conjugated), RH-0294 and the hydroxylactone in eggs and animal tissues. The sensitivity of such method(s) should be $\leq$ 0.01 ppm, if possible.

FDA multiresidue information via protocols I thru IV has been submitted for RH-3866 and RH-9090 (free). Testing through these four protocols is also required of the other components of the regulable residue: RH-9090 (conjugated), RH-0294, and the hydroxylactone.

The petitioner is urged to look into the possibility of consolidating proposed enforcement methods for myclobutanil and metabolites into one or two "total residue" methods applicable to determining the regulable residue in crops and animal commodities (meat, milk, and eggs).

PETITIONER'S RESPONSE: Residue Analytical Methods [MAM 88-19]

The petitioner states, "We believe available analytical methods for RH-3866, RH-9090, and diol are adequate to enforce the proposed tolerances...." And, further, "We invariably strive to develop residue analytical methodology capable of measuring the total toxic residue in a single method. We accomplished this objective for apples and grapes, and their corresponding processed fractions. It was possible to convert by a combination of hydrolysis and reduction all plant metabolites to RH-9090. For animal metabolites, however, the structures do not readily suggest a common moiety around which to streamline an analytical method for enforcement purposes."

RCB's COMMENTS/CONCLUSIONS: Residue Analytical Methods

We continue to withhold judgment on the adequacy of the aforecited submitted analytical methods for residue data gathering and/or enforcement purposes pending completion of petition method validation (PMV) trials by COB/BUD chemists, review by RCB of COB's reports on such trials, corrective action (where needed) on the petitioner's part, and reevaluation by RCB (and, if warranted, COB).

To date, two PMVs have been run. RH-3866 and RH-9090 in apples (TR 310-84-27, with Addendums TR 31H-86-15 and TR 31S-87-46); and, RH-3866 in meat and milk (TR 310-84-13, with Addendum TR 310-86-09). Difficulties were encountered in both PMVs. (See the RCB reviews of 4/12/88 and 4/14/88.) Revised methodology has not yet been received for evaluation.

Two additional PMVs are currently being run: RH-9090 (free) in meat and milk (TR 31S-87-09); and, RH-0294 (diol) in milk (TR 31S-87-02). A June completion date is projected.

Based on the RCB and TOX decisions on the regulable residue (see TOX review of 4/5/88 and RCB review of 4/14/88), residue analytical methods are no longer being requested in re this petition for the hydroxylactone and diol (RH-0294) metabolites, or for RH-9090 (bound) in animal tissues other than milk.

A residue analytical method needs to be submitted for the determination of RH-9090 (bound) in milk.

We consider the FDA multiresidue information which has been submitted for RH-9090 (free) to be applicable to RH-9090 (bound).

CONCLUSION: Outstanding deficiencies remain to be resolved in the area of residue analytical methods.

DEFICIENCY: Storage Stability

The following additional storage stability data are needed:

- RH-9090 (free and conjugated) in apples and grapes.
- RH-3866 in apple pomace; grape pomace; raisin waste; and raisins. (This requirement only applies if these processing fractions were frozen-stored for longer than two weeks prior to analysis.)
- RH-9090 (free and conjugated) in apple pomace; grape pomace; raisin waste; and raisins. (This requirement only applies if these processing fractions were frozen-stored for longer than two weeks prior to analysis.)

The length of the storage stability studies on these matrices/compounds should be of sufficient duration to validate the crop field trial and processing study data on apples and grapes; i.e., if crop field trial and processed food/feed samples were stored 9 months prior to residue analysis, then a 9-month (minimum) storage stability study to validate the storage of those samples is required.

PETITIONER'S RESPONSE: Storage Stability [MRID# 405481-01]

Re the requested information for RH-9090 (free and bound) in apples and grapes, the petitioner rationalizes [TR 34S-88-11] such data are not needed, based on:

- Hydrolytic and oxidative decomposition comprise the only plausible chemical pathways for degradation of residues in a solidly frozen crop sample, and myclobutanil contains no structural elements subject to such degradation under all but the most drastic conditions.

- RH-9090 is identical to myclobutanil except for the introduction of a hydroxyl group onto the aliphatic side chain;

- Myclobutanil has demonstrated its stability during frozen storage;

- Their experience that RH-9090 is as hydrolytically stable as the parent compound;

- The fact that, were RH-9090 to be oxidized, it would yield RH-9089, which is also quantified by the total residue method;

- The fact that, were RH-9090 (bound) to degrade, free RH-9090 would be the resulting product;

- Were RH-9090 to be degrading during storage, the percent of total residue quantified as RH-9090 would vary with the period of storage; an analysis of the previously submitted residue field trial data for apples and grapes (see summary, Tables 17 and 19 of RCB review, 2/8/88) shows that RH-9090 (total) comprised a constant percentage of the total residue, independent of storage interval:

Crop	Length of Storage Before Analysis	% of Total Residue Quantified as RH-9090
Apples	0-2 months	22.1%
	9-10 months	22.1%
Grapes	0-2 weeks	14.1%
	0-2 months	15.8%
	9-10 months	14.4%

These data also illustrate that the largest portion of the residue consists of parent compound, for which long term storage stability has been demonstrated.

- Reanalysis of samples of both apples and grapes, previously analyzed soon after harvest, demonstrates the stability of myclobutanil and RH-9090 (total) residues during even prolonged periods (>3 years) of frozen storage:

Test Code	Sample No.	ppm Residue[1] RH-3866	RH-9090	Total	Harvest to Analysis, Days
84-0241	004	0.155	0.094	0.249	24
Apples	004	0.160	0.108	0.268	1264
	005	0.074	0.073	0.147	24
	005	0.087	0.073	0.160	1264
84-0300	001	0.036	0.012	0.048	37
Apples	001	0.039	0.011	0.050	1257
	002	0.029	0.024	0.053	37
	002	0.036	0.034	0.070	1257
86-0175	001	0.085	0.022	0.107	6
Grapes	001	0.104	0.026	0.130	6
	001	0.083	0.030	0.113	629
	002	0.094	0.024	0.118	6
	002	0.081	0.022	0.103	629
86-0231	002	0.087	0.025	0.112	48
Grapes	002	0.096	0.029	0.125	609
	003	0.088	0.024	0.112	48
	003	0.092	0.022	0.114	609

[1] Reanalyses employed the RH-3866 Total Residue Method for Apples and Grapes (TR 310-84-27), as modified in Addendum 2 (TR 31S-87-46). RH-9090 is "total" RH-9090 (free and bound). Supporting chromatograms in TR 34S-88-11.

Re the requested information for RH-3866 and RH-9090 (free and bound) in processed fractions of apples and grapes, the petitioner rationalizes [TR 34S-88-11] such data are not needed, based on:

- Storage stability data are available showing no degradation of myclobutanil (RH-3866) in apples, grapes, wheat, and soil;

- It has now been demonstrated that residues quantified as RH-9090 (total) are as stable as myclobutanil residues;

- Since storage stability data on unrelated commodities show similar results, they can be translated to support the stability of the processed fractions, which are "closely related" commodities (see Agency position document on Storage Stability, 9/87);

- Independent verification of the stability of RH-3866 related residues in the processed commodities is available from the submitted processing studies. For each crop, apple and grape, two different processing studies are reported. As shown below, the samples from the two studies for each crop differ greatly in the length of time between processing and analysis:

Crop	Test Code	Acces. No.	Date Processed	Processing-to-Analysis Interval
Apple	85-0542	266031	5/12/86	10 weeks
	84-0238	266105	9/17/84	19 months
Grape	85-0419	266032	9/17/85	8 weeks
	85-0323	266032	8/29/85	11 months

The concentration factors in these processing studies for each crop show consistency (see Tables 18 and 20, RCB New Chemical Residue Chemistry Review of Myclobutanil, 2/8/88). Since, for each crop, these concentration factors were determined from samples varying widely in the period of frozen storage prior to analysis, these demonstrate the stability of residues during the storage period.

RCB's COMMENTS/CONCLUSIONS: Storage Stability

RCB considers the petitioner has adequately supported his claim that the storage stability data requested are not needed.

CONCLUSION: This storage stability deficiency is considered resolved.

DEFICIENCY: Magnitude of the Residue - Apples

Crop Field Trials

The proposed tolerance on apples is 0.5 ppm for combined residues of the parent (RH-3866) and RH-9090 (free and bound). Tentatively, we conclude these field trial data support the proposed tolerance, and that 0.5 ppm is an appropriate level.

Before we can finalize our conclusion about the adequacy of these field trial data to support the proposed tolerance on apples, storage stability data for RH-9090 (free and bound) residues in apples must be submitted and method validations must be successfully completed.

Processed Food and Feed

We withhold judgment on the adequacy of the apple processing studies until storage stability data for residues of RH-9090 (free and bound) in apples are submitted and method validations have been successfully completed.

Also, the date on which processing of apples occurred [TR 31H-86-09; MRID/Acces.# 266031] needs to be provided.

Raw data, processing information, and date of processing, also need to be submitted for the processing of apples from crop field trial 84-0238 [summarized in MRID/Acces.# 266105].

If apple processing fractions were frozen-stored for longer than 2 weeks prior to analysis, storage stability data of appropriate duration for RH-3866 and RH-9090 (free and conjugated) residues in apple processing fractions will also be needed.

Tentatively, we consider a feed additive tolerance proposal based on < 10X concentration factor in apple pomace to be appropriate.

PETITIONER'S RESPONSE: Magnitude of the Residue - Apples

The storage stability issue has been addressed (see PETITIONER'S RESPONSE: Storage Stability).

Processing dates are submitted [MRID# 405481-01: TR 34S-88-11, p. 8.] Apples from study 85-0542 were processed 5/12/86 and, from study 84-0238, 9/17/84.

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RCB'S COMMENTS/CONCLUSIONS: Magnitude of the Residue - Apples

Final judgment on the adequacy of the submitted field trial and processing study data, and on the level of proposed tolerances, must await a final decision on the adequacy of the analytical methods for generating these submitted data and for enforcing the proposed tolerances on apples and apple pomace.

The petitioner should submit the raw data from the processing of apples from crop field trial 84-0238 [summarized in MRID/ Acces.# 266105], if these data are available.

CONCLUSION: Only tentative conclusions can be reached at this time re the adequacy of submitted field trial and processing study data and proposed tolerance levels, pending PMV results and evaluation. Tentatively, it appears appropriate tolerance levels will be 0.5 ppm for apples and 5.0 ppm for apple pomace.

The petitioner should submit the raw data requested (for apple trial 84-0238), if available.

DEFICIENCY: Magnitude of the Residue - Grapes

Crop Field Trials

The proposed tolerance on grapes is 1.0 ppm for combined residues of the parent (RH-3866) and RH-9090 (free and bound). Tentatively, we conclude these field trial data support the proposed tolerance, and that 1.0 ppm is an appropriate level.

Before we can finalize our conclusion about the adequacy of these field trial data to support the proposed tolerance on grapes, storage stability data for RH-9090 (free and bound) residues in grapes must be submitted and method validations must be successfully completed.

Processed Food and Feed

We withhold judgment on the adequacy of the grape processing studies until storage stability data for residues of RH-9090 (free and bound) in grapes are submitted and method validations have been successfully completed.

Also, the dates on which processing of grapes occurred [TR 31H-86-11; MRID/Acces.# 266032] needs to be provided.

If grape processing fractions were frozen-stored for longer than two weeks prior to analysis, storage stability data of appropriate duration for RH-3866 and RH-9090 (free and conjugated) residues in grape processing fractions will also be needed.

Tentatively, we consider food and feed additive tolerance proposals based on < 10X concentration in raisins and grape pomace and ≤ 25X concentration in raisin waste to be appropriate. "

PETITIONER'S RESPONSE: Magnitude of the Residue - Grapes

The storage stability issue has been addressed (see PETITIONER'S RESPONSE: Storage Stability).

Processing dates are submitted [MRID# 405481-01: TR 34S-88-11, p. 8.] Grapes from study 85-0419 were processed 9/17/85 and, from study 85-0323, 8/29/85.

RCB'S COMMENTS/CONCLUSIONS: Magnitude of the Residue - Grapes

Final judgment on the adequacy of the submitted field trial and processing study data, and on the level of proposed tolerances, must await a final decision on the adequacy of the analytical methods for generating these submitted data and for enforcing the proposed tolerances on grapes, grape pomace, raisins, and raisin waste.

CONCLUSION: Only tentative conclusions can be reached at this time re the adequacy of submitted field trial and processing study data and proposed tolerance levels, pending PMV results and evaluation. Tentatively, it appears appropriate tolerance levels will be 1.0 ppm for grapes, 10.0 ppm for grape pomace and raisins, and 25 ppm for raisin waste.

DEFICIENCY: Magnitude of the Residue - Cattle

Adequate feeding study data have been submitted for lactating dairy cattle (ruminant).

At the dietary burden (4.5-5.5 ppm/day to cattle) associated with the proposed use on apples and grapes, appropriate tolerances will be 0.05 ppm for milk and the meat,

fat, and meat by-products (except liver) of cattle, goats, hogs, horses, and sheep; and, 0.3 ppm for liver of cattle, goats, hogs, horses, and sheep.

This conclusion is contingent upon successful PMVs for the components of the regulable residue being conducted by COB/BUD, and demonstrating an adequate level of recovery and sensitivity at (or below) these suggested tolerance levels.

A revised Section F proposing appropriate tolerances for the regulable residue will need to be submitted.

PETITIONER'S RESPONSE: Magnitude of the Residue - Cattle

No specific response was made to this topic. In a related area (see PETITIONER'S RESPONSE: Proposed Tolerances section of this review), the petitioner did request [MAM 88-19] that RCB revisit its position re what the regulable residue should be comprised of in animal commodities (see RCB'S COMMENTS/CONCLUSIONS: Proposed Tolerances section of this review).

RCB'S COMMENTS/CONCLUSIONS: Magnitude of the Residue - Cattle

Our position remains as stated above (see DEFICIENCY: Magnitude of the Residue - Cattle).

DEFICIENCY: Magnitude of the Residue - Poultry

Adequate feeding study data have been submitted for laying hens (poultry).

At the dietary burden (0.75 ppm/day to poultry) associated with the proposed use on apples and grapes, appropriate tolerances will be 0.02 ppm for eggs and the meat, fat, and meat by-products of poultry.

This conclusion is contingent upon successful PMVs for the components of the regulable residue being conducted by COB/BUD, and demonstrating an adequate level of recovery and sensitivity at (or below) these suggested tolerance levels.

A revised Section F proposing appropriate tolerances for the regulable residue will need to be submitted.

PETITIONER'S RESPONSE: Magnitude of the Residue - Poultry

The petitioner requested [MAM 88-19] RCB reconsider the need to establish tolerances in poultry tissues and eggs in conjunction with this petition.

The petitioner also requested [MAM 88-19] RCB reexamine its position re what the regulable residue should be comprised of in animal commodities.

RCB'S COMMENTS/CONCLUSIONS: Magnitude of the Residue - Poultry

Our responses to the issues of setting tolerances for poultry tissues/eggs and the composition of the regulable residue for animal commodities are given in the RCB'S COMMENTS/CONCLUSIONS: Proposed Tolerances section of this review, which see.

Our position remains as stated above (see DEFICIENCY: Magnitude of the Residue - Poultry).

OTHER CONSIDERATIONS

By transmittal letter of 3/11/88, the petitioner submitted a set of revised Confidential Statements of Formula (EPA Form 8570-4) for:

707-ERN	RH-3866 Technical
707-ERE	RALLY™ 40W Fungicide
707-ERL	RALLY™ 40W Fungicide in 4 oz. Water-Soluble Pouches
707-ERR	RALLY™ 60DF Fungicide
707-EER	NOVA® 40W Fungicide in 5 oz. Water-Soluble Pouches

The inert ingredients in the formulated products are unchanged. The percent active ingredient is slightly higher than previously reported, based on additional batch analyses by the petitioner of RH-3866 Technical. The CSF for RH-3866 Technical also lists [redacted] not originally reported. (See related RCB review on Product Chemistry of RH-3866 Technical, as revised 4/11/88.)

* * *

The petitioner requested (2/1/88 letter) dietary exposure estimates be taken into consideration in the Agency's reconsideration of the regulable residue in animal commodities. TOX and RCB (including RCB's TAS unit) have discussed this. It was concluded this did not affect TOX's determination of the need to regulate RH-9090 (bound) in milk.

cc: Reading File
Circulation
PP#7F3476/FAP#7H5524
Myclobutanil Registration Standard File
M. Nelson (RCB)
H. Jacoby (SPMS)
ISB/PMSD (Eldredge)

TS-769C:RCB:Reviewer(MJN):CM#2:Rm804:557-7324:typist(mjn):4/24/88.

RDI:SectionHead:RSQuick:4/25/88:DeputyChief:RDSchmitt:4/25/88.